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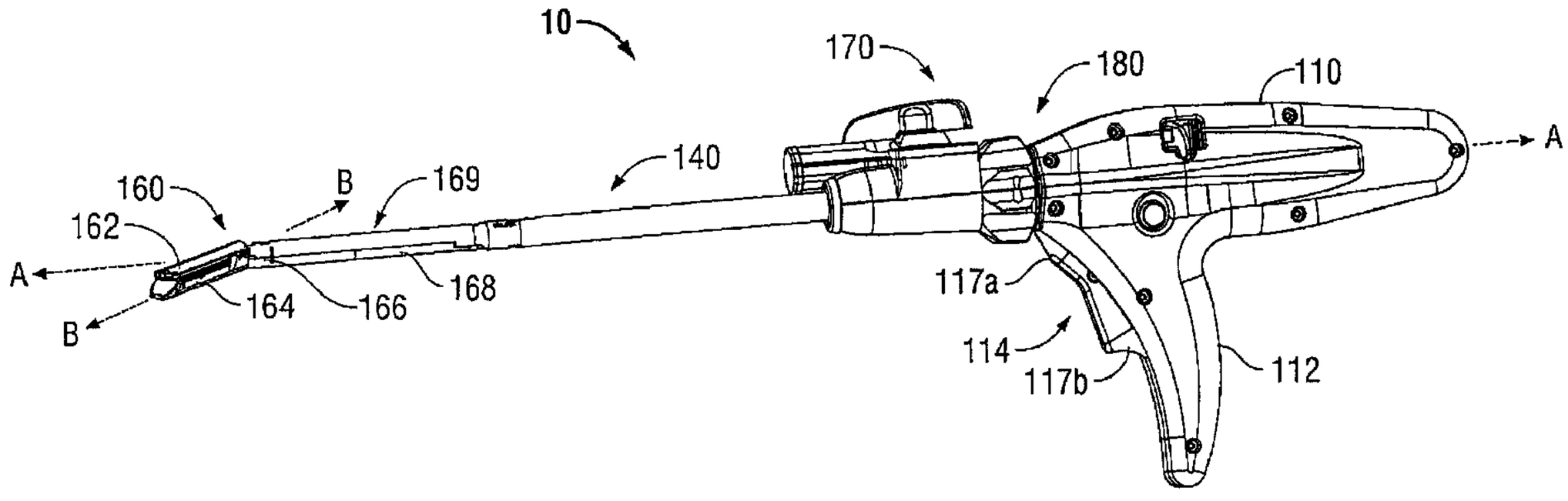
(54) **Titre : APPAREILLAGE ET METHODE PERMETTANT DE RETRAITER UN INSTRUMENT CHIRURGICAL ELECTRIQUE**
(54) **Title: SYSTEM AND METHOD FOR PREVENTING REPROCESSING OF A POWERED SURGICAL INSTRUMENT**



(57) **Abrégé/Abstract:**
A surgical instrument is disclosed. The instrument includes a microcontroller coupled to a memory, the microcontroller is configured to control the surgical instrument and a usage counter stored in the memory that is incremented when the surgical instrument is activated, wherein the microcontroller is further configured to prevent actuation of the surgical instrument when the usage counter is above a predetermined threshold.

ABSTRACT

A surgical instrument is disclosed. The instrument includes a microcontroller coupled to a memory, the microcontroller is configured to control the surgical instrument and a usage counter stored in the memory that is incremented when the surgical instrument is activated, wherein the microcontroller is further configured to prevent actuation of the surgical instrument when the usage counter is above a predetermined threshold.

SYSTEM AND METHOD FOR PREVENTING REPROCESSING OF A POWERED SURGICAL INSTRUMENT

BACKGROUND

Technical Field

The present disclosure relates to a surgical instrument. More particularly, the present disclosure relates to a surgical instrument which includes a mechanism for preventing reprocessing of the instruments and components thereof.

Background of Related Art

Current known devices can typically require 10-60 pounds of manual hand force to clamp tissue and deploy and form surgical fasteners in tissue which, over repeated use, can cause a surgeon's hand to become fatigued. Gas powered pneumatic staplers which implant surgical fasteners into tissue are known in the art. Certain of these instruments utilize a pressurized gas supply which connects to a trigger mechanism. The trigger mechanism, when depressed, simply releases pressurized gas to implant a fastener into tissue.

Motor-powered surgical staplers are also known in the art. These include powered surgical staplers having motors which activate staple firing mechanisms. However, these motor

powered devices only provide for limited user control of the stapling process. The user can only toggle a single switch and/or button to actuate the motor and applies corresponding torque to the stapler's firing mechanisms. In certain other devices, a controller is used to control the stapler.

There is a continual need for new and improved powered surgical staplers which include various sensors. The sensors provide relevant feedback to feedback controllers which automatically adjust various parameters of the powered stapler in response to sensed feedback signals representative of stapler operation, including articulation and actuation of the tool assemblies.

SUMMARY

According to one aspect of the present disclosure, a surgical instrument is disclosed, which includes a microcontroller coupled to a memory, the microcontroller is configured to control the surgical instrument and a usage counter stored in the memory that is incremented when the surgical instrument is activated, wherein the microcontroller is further configured to prevent actuation of the surgical instrument when the usage counter is above a predetermined threshold.

According to another aspect of the present disclosure, a surgical instrument is disclosed, which includes a microcontroller coupled to a memory, the microcontroller is configured to control the surgical instrument and a sterilization counter stored in the memory that is incremented when the surgical instrument is sterilized, wherein the microcontroller is further configured to prevent actuation of the surgical instrument when the sterilization counter is above a predetermined threshold.

According to a further aspect of the present disclosure, a surgical instrument is disclosed, which includes at least one component including a component microcontroller configured to store an identifier corresponding to the at least one component and a microcontroller coupled to a memory, the microcontroller is configured to control the surgical instrument and to authenticate the at least one component based on a response to a challenge request, wherein the response includes the identifier.

In accordance with one embodiment of the present invention, there is provided a surgical instrument, comprising: a housing; at least one component disposed within the housing and including a component microcontroller configured to store a unique identifier associated with the at least one component; an instrument microcontroller coupled to a memory, the instrument microcontroller configured to control the surgical instrument, the instrument microcontroller configured to send a challenge request to the component microcontroller of the at least one component to authenticate the at least one component by comparing the unique identifier associated with the component microcontroller of the at least one component with a pre-approved set of identifiers; and a usage counter stored in the memory and configured to generate a count of a number of uses of the surgical instrument, the count incremented when the surgical instrument is activated, the microcontroller configured to prevent actuation of the surgical instrument when the count is above a predetermined use threshold of the surgical instrument.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the subject instrument are described herein with reference to the drawings wherein:

Fig. 1 is a perspective view of a powered surgical instrument according to an embodiment of the present disclosure;

Fig. 2 is a partial enlarged perspective view of the powered surgical instrument of Fig. 1 according to the embodiment of the present disclosure;

Fig. 3 is a partial enlarged plan view of the powered surgical instrument of Fig. 1 according to the embodiment of the present disclosure;

Fig. 4 is a partial perspective sectional view of internal components of the powered surgical instrument of Fig. 1 according to the embodiment of the present disclosure;

Fig. 5 is a schematic diagram of a controller circuit according to the embodiment of the present disclosure; and

Fig. 6 is a flow chart of a method according to the embodiment of the present disclosure.

DETAILED DESCRIPTION

Embodiments of the presently disclosed powered surgical instrument are now described in detail with reference to the drawings, in which like reference numerals designate identical or corresponding elements in each of the several views. As used herein the term "distal" refers to that portion of the powered surgical instrument, or component thereof, farther from the user while the term "proximal" refers to that portion of the powered surgical instrument or component thereof, closer to the user.

A powered surgical instrument, e.g., a surgical stapler, in accordance with the present disclosure is referred to in the figures as reference numeral 10. Referring initially to Fig. 1, powered surgical instrument 10 includes a housing 110, an endoscopic portion 140 defining a first longitudinal axis A-A extending therethrough, and an articulating tool assembly (e.g., end effector 160), defining a second longitudinal axis B-B extending therethrough. Endoscopic portion 140 extends distally from housing 110 and the end effector 160 is disposed adjacent a distal portion of endoscopic portion 140. In an embodiment, the components of the housing 110 are sealed against infiltration of particulate and/or fluid contamination and help prevent damage of the components by sterilization processes.

According to an embodiment of the present disclosure, end effector 160 includes a first jaw member having one or more surgical fasteners (e.g., cartridge assembly 164) and a second opposing jaw member including an anvil portion for deploying and forming the surgical fasteners (e.g., an anvil assembly 162). In certain embodiments, the staples are housed in cartridge assembly 164 to apply linear rows of staples to body tissue either in simultaneous or sequential manner. Either one or both of the anvil assembly 162 and the cartridge assembly 164 are movable in relation to one another between an open position, in which the anvil assembly

162 is spaced from cartridge assembly 164, and an approximated or clamped position, in which the anvil assembly 162 is in juxtaposed alignment with cartridge assembly 164.

It is further envisioned that end effector 160 is attached to a mounting portion 166, which is pivotably attached to a body portion 168. Body portion 168 may be integral with endoscopic portion 140 of powered surgical instrument 10, or may be removably attached to the instrument 10 to provide a replaceable, disposable loading unit (DLU) or single use loading unit (SULU) (e.g., loading unit 169). In certain embodiments, the reusable portion may be configured for sterilization and re-use in a subsequent surgical procedure.

The loading unit 169 may be connectable to endoscopic portion 140 through a bayonet connection. It is envisioned that the loading unit 169 has an articulation link connected to mounting portion 166 of the loading unit 169 and the articulation link is connected to a linkage rod so that the end effector 160 is articulated as the linkage rod is translated in the distal-proximal direction along first longitudinal axis A-A as discussed in more detail below. Other means of connecting end effector 160 to endoscopic portion 140 to allow articulation may be used, such as a flexible tube or a tube comprising a plurality of pivotable members.

The loading unit 169 may incorporate or be configured to incorporate various end effectors, such as vessel sealing devices, linear stapling devices, circular stapling devices, cutters, graspers, etc. Such end effectors may be coupled to endoscopic portion 140 of powered surgical instrument 10. An intermediate flexible shaft may be included between handle portion 112 and loading unit. It is envisioned that the incorporation of a flexible shaft may facilitate access to and/or within certain areas of the body.

With reference to Figs. 1 and 2, an enlarged view of the housing 110 is illustrated according to an embodiment of the present disclosure. In the illustrated embodiment, housing

110 includes a handle portion 112 having a main drive switch 114 disposed thereon. The switch 114 may include first and second switches 114a and 114b formed together as a toggle switch. The handle portion 112, which defines a handle axis H-H, is configured to be grasped by fingers of a user. The handle portion 112 has an ergonomic shape providing ample palm grip leverage which helps prevent the handle portion 112 from being squeezed out of the user's hand during operation. Each switch 114a and 114b is shown as being disposed at a suitable location on handle portion 112 to facilitate its depression by a user's finger or fingers.

Additionally, and with reference to Figs. 1 and 2, switches 114a, 114b may be used for starting and/or stopping movement of drive motor 200 (Fig. 4). In one embodiment, the switch 114a is configured to activate the drive motor 200 in a first direction to advance firing rod (not explicitly shown) in a distal direction thereby approximating the anvil and the cartridge assemblies 162 and 164. Conversely, the switch 114b may be configured to retract the firing rod to open the anvil and cartridge assemblies 162 and 164 by activating the drive motor 200 in a reverse direction. The retraction mode initiates a mechanical lock out, preventing further progression of stapling and cutting by the loading unit 169. The toggle has a first position for activating switch 114a, a second position for activating switch 114b, and a neutral position between the first and second positions.

The housing 110, in particular the handle portion 112, includes switch shields 117a and 117b. The switch shields 117a and 117b may have a rib-like shape surrounding the bottom portion of the switch 114a and the top portion of the switch 114b, respectively. The switch shield 117a and 117b prevent accidental activation of the switch 114. Further, the switches 114a and 114b have high tactile feedback requiring increased pressure for activation.

In one embodiment, the switches 114a and 114b are configured as multi-speed (e.g., two or more), incremental or variable speed switches which control the speed of the drive motor 200 and the firing rod in a non-linear manner. For example, switches 114a, 114b can be pressure-sensitive. This type of control interface allows for gradual increase in the rate of speed of the drive components from a slower and more precise mode to a faster operation. To prevent accidental activation of retraction, the switch 114b may be disconnected electronically until a fail safe switch 114c is pressed.

The switches 114a and 114b are coupled to a non-linear speed control circuit which can be implemented as a voltage regulation circuit, a variable resistance circuit, or a microelectronic pulse width modulation circuit. The switches 114a and 144b may interface with the control circuit by displacing or actuating variable control devices, such as rheostatic devices, multiple position switch circuit, linear and/or rotary variable displacement transducers, linear and/or rotary potentiometers, optical encoders, ferromagnetic sensors, and Hall Effect sensors. This allows the switches 114a and 114b to operate the drive motor 200 in multiple speed modes, such as gradually increasing the speed of the drive motor 200 either incrementally or gradually depending on the type of the control circuit being used, based on the depression of the switches 114a and 114b.

Figs. 2-4 illustrate an articulation mechanism 170, including an articulation housing 172, a powered articulation switch 174, an articulation motor 132 and a manual articulation knob 176. Translation of the powered articulation switch 174 or pivoting of the manual articulation knob 176 activates the articulation motor 132 which then actuates an articulation gear 233 of the articulation mechanism 170 as shown in Fig. 4. Actuation of articulation mechanism 170 causes the end effector 160 to move from its first position, where longitudinal axis B-B is substantially

aligned with longitudinal axis A-A, towards a position in which longitudinal axis B-B is disposed at an angle to longitudinal axis A-A. The powered articulation switch 174 may also incorporate similar non-linear speed controls as the clamping mechanism. These can be controlled by the switches 114a and 114b.

With reference to Figs. 2 and 3, the housing 110 includes switch shields 169 having a wing-like shape and extending from the top surface of the housing 110 over the switch 174. The switch shields 169 prevent accidental activation of the switch 174 and require the user to reach below the shield 169 in order to activate the articulation mechanism 170.

Additionally, articulation housing 172 and powered articulation switch 174 are mounted to a rotating housing assembly 180. Rotation of a rotation knob 182 about first longitudinal axis A-A causes housing assembly 180 as well as articulation housing 172 and powered articulation switch 174 to rotate about first longitudinal axis A-A, and thus causes corresponding rotation of distal portion 224 of firing rod 220 and end effector 160 about first longitudinal axis A-A. The articulation mechanism 170 is electro-mechanically coupled to one or more conductive rings that are disposed on a housing nose assembly 155 (Fig. 4). The conductive rings may be soldered and/or crimped onto the nose assembly 155 and are in electrical contact with a power source 300 thereby providing electrical power to the articulation mechanism 170. The nose assembly 155 may be modular and may be attached to the housing 110 during assembly to allow for easier soldering and/or crimping of the rings. The articulation mechanism 170 may include one or more brush and/or spring loaded contacts in contact with the conductive rings such that as the housing assembly 180 is rotated along with the articulation housing 172 the articulation mechanism 170 is in continuous contact with the conductive rings thereby receiving electrical power from the power source 300.

Further details of articulation housing 172, powered articulation switch 174, manual articulation knob 176 and providing articulation to end effector 160 are described in detail in commonly-owned U.S. Patent Application Publication Serial No. 2008/0223903.

It is envisioned that any combinations of limit switches, proximity sensors (e.g., optical and/or ferromagnetic), linear variable displacement transducers and shaft encoders which may be disposed within housing 110, may be utilized to control and/or record an articulation angle of end effector 160 and/or position of the firing rod 220.

As shown in Fig. 4, the instrument 10 also includes a microcontroller 400 electrically coupled to the motor 200 and various sensors disposed in the instrument 10. The sensors detect various operating parameters of the instrument 10 (e.g., linear speed, rotation speed, articulation position, temperature, battery charge, and the like), which are then reported to the microcontroller 400. The microcontroller 400 may then respond accordingly to the measured operating parameters (e.g., adjust the speed of the motor 200, control articulation angle, shut-off the power supply, report error conditions, etc.).

With reference to Fig. 5, a controller circuit 401 is shown. The controller circuit 401 includes the microcontroller 400 that is coupled to a memory 402 (e.g., non-volatile memory), which stores one or more software applications (e.g., firmware) for controlling the operation and functionality of the instrument 10. The microcontroller 400 processes input data from the user interface and adjusts the operation of the instrument 10 in response to the inputs. The adjustments to the instrument 10 may include powering the instrument 10 on or off, speed control by means of voltage regulation or voltage pulse width modulation, torque limitation by

reducing duty cycle or pulsing the voltage on and off to limit average current delivery during a predetermined period of time.

In one embodiment, the microcontroller 400 and the memory 402 may be integrated into an application-specific integrated circuit ("ASIC") customized for control of the instrument 10. In another embodiment, the microcontroller 400 may be a one-time programmable ("OTP") microcontroller to prevent new code or firmware being written onto the microcontroller 400. The use of OTP and ASIC prevents unauthorized re-processors from rewriting the code controlling the instrument 10 and overriding the usage limitations discussed below.

It is envisioned that the instrument 10 may be used only a predetermined number of times. In other words, it is desirable to limit the number of reuses to a number mandated by the manufacturer or to ensure that a single-use instrument is only used once. With reference to Fig. 5, the microcontroller 400 is configured to maintain a usage counter 403 for counting the number of times the instrument 10 has been used. The usage counter 403 is stored in the memory 402. The microcontroller 400 may determine the number of uses based on the number of activations of the motor 200, the number of firing strokes performed by the motor 200, and length of operation for each activation. The usage counter 403 is initialized at zero prior to the instrument 10 being used for the first time and may not be reset by third parties. The usage counter 403 is incremented by the microcontroller 400 whenever the microcontroller 400 determines that the instrument 10 has been activated. In one embodiment, the usage counter 403 may be encrypted to prevent resetting of the counter 403. The usage counter 403 may also be a timer that records the time that the instrument 10 has been used. The total usage time is also recorded in the memory 402. Prior to activation of the instrument 10, the microcontroller 400 determines if the

usage counter 403 is below a predetermined usage threshold. If the usage counter 403 exceeds the threshold, the microcontroller 400 prevents activation of the instrument 10.

In another embodiment, the microcontroller 400 is configured to maintain a sterilization counter 405 in the memory 402, if a certain number of re-uses of the instrument 10 are advised. The sterilization counter 405 may be implemented in conjunction with the usage counter 403. The sterilization counter 405 is also stored in the memory 402 and maintains a number of times the instrument 10 has been sterilized.

As shown in Fig. 4, the instrument 10 includes a sterilization sensor 410 (e.g., temperature sensor 406 and/or a moisture sensor 408), which detect when the instrument 10 has passed through a sterilization cycle. The temperature sensor 406 may be a thermistor, a thermopile, a thermocouple, a thermal infrared sensor, a resistance temperature detector, a linear active thermistor, a bimetallic contact switch, and the like. The moisture sensor 408 may be of capacitive, resistive and thermal conductivity types. The temperature and moisture sensors 406 and 408 are coupled to the microcontroller 400 and/or the memory 402 and are configured to increment the sterilization counter when the temperature and/or moisture are detected to be above predetermined thresholds (e.g., temperatures above 80° C and humidity above 60%). The temperature and moisture sensors 406 and 408 may be integrated into the ASIC with the microcontroller 400 and the memory 402 to prevent tampering.

In another embodiment, the sterilization counter 405 may be encrypted to prevent resetting of the sterilization counter 405. Prior to activation of the instrument 10, the microcontroller 400 determines if the sterilization counter 405 is below a predetermined usage threshold. If the sterilization counter 405 exceeds the threshold, the microcontroller 400 prevents activation of the instrument 10.

With the modular design of the instrument 10, certain components 412 of the instrument 10 (e.g., motor 200, power source 300, loading unit 169, etc.) may be replaced during the life-time of the instrument 10. However, such modularity also provides unauthorized reuse of the instrument 10 by replacing the components 412. To prevent unauthorized replacement of the components 412, each of the components 412 may include an identifier 414 (Fig. 5) associated therewith. The identifiers 414 may be any value stored in a memory and/or component microcontroller 416 of the component that can be read by the microcontroller 400, such as a serial number. The microcontroller 416 may be coupled through wired and/or wireless communication protocols to the microcontroller 400 of the instrument 10 to authenticate the component 412. The identifier 414 may be encrypted to prevent unauthorized reading of the identifier. In another embodiment, the identifier may be a unique electrical measurable value of the component 412 (e.g., resistance, capacitance, inductance, etc.).

To ensure that only authorized components 412 are used in the instrument 10, the microcontroller 400 may execute a so-called challenge-response authentication algorithm as shown in Fig. 6. In step 500, the microcontroller 400 sends a challenge request to the component microcontroller 408. In step 502, the microcontroller 416 interprets the challenge request and generates a response as a reply to the request. The response includes the identifier 414 and may be encoded using a first pair of an encryption key that is specific to the microcontroller 416. In step 504, the microcontroller 400 receives the reply and decodes the identifier 414 using a second pair of the key. In step 506, the microcontroller 400 determines if the component 412 is authentic based on the identifier 414, by comparing the identifier 414 with a pre-approved list of authentic identifiers. If the identifier is not valid, in step 507, microcontroller 400 prevents

activation of the instrument 10. If the identifier is valid, the process proceeds to step 508, the instrument 10 commences operation.

The above-discussed systems and method for controlling usage of the instrument 10 and components 412 thereof may be combined in a unitary authentication process. The usage counter 403, the sterilization counter 405 and the response to the authentication algorithm may be combined in a single value stored in the memory 402 as a so-called "device status word" ("DSW"). Upon power-up of the instrument 10, the microcontroller 400 checks the DSW to determine if the instrument 10 may be unlocked. This involves a determination whether the usage counter 403 and the sterilization counter 405 are below a predetermined usage threshold and whether all of the components 412 are authentic. In addition, an authentication flag may be set in the DSW that prevents activation of the instrument 10 if any of the components 412 are found to be inauthentic. If either the usage or the sterilization counters 403 and 405 are above the thresholds or the authentication flag is activated, the microcontroller 400 prevents activation of the instrument 10. The DSW may be continually updated prior to activation of the instrument 10. The DSW may also be encrypted to prevent unauthorized access and tampering.

It will be understood that various modifications may be made to the embodiments shown herein. Therefore, the above description should not be construed as limiting, but merely as exemplifications of preferred embodiments. Although specific features of the powered surgical instrument are shown in some of the drawings and not in others, this is for convenience only as each feature may be combined with any or all of the other features in accordance with the aspects of the present disclosure. Other embodiments will occur to those skilled in the art and are within the following claims.

The embodiments of the present invention for which an exclusive property or privilege is claimed are defined as follows:

1. A surgical instrument, comprising:

a housing;

at least one component disposed within the housing and including a component microcontroller configured to store a unique identifier associated with the at least one component;

an instrument microcontroller coupled to a memory, the instrument microcontroller configured to control the surgical instrument, the instrument microcontroller configured to send a challenge request to the component microcontroller of the at least one component to authenticate the at least one component by comparing the unique identifier associated with the component microcontroller of the at least one component with a pre-approved set of identifiers; and

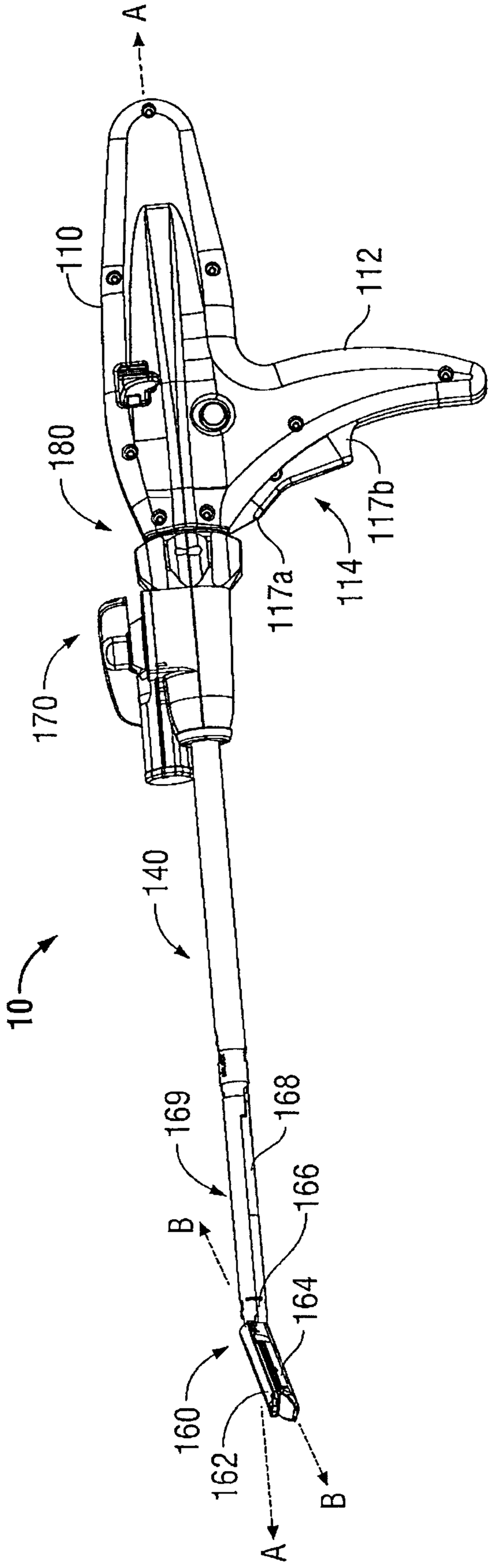
a usage counter stored in the memory and configured to generate a count of a number of uses of the surgical instrument, the count incremented when the surgical instrument is activated, the microcontroller configured to prevent actuation of the surgical instrument when the count is above a predetermined use threshold of the surgical instrument.

2. The surgical instrument according to claim 1, wherein the instrument microcontroller is a one-time programmable microcontroller.

3. The surgical instrument according to claim 1 or 2, wherein the instrument microcontroller and the memory are integrated in an application-specific integrated circuit.

4. The surgical instrument according to any one of claims 1 to 3, wherein the usage counter includes a timer.

5. The surgical instrument according to any one of claims 1 to 4, wherein the usage counter is encrypted.


A
110
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117a
114
117b
10
140
169
168
B
166
164
160
162
A
B

FIG. 1

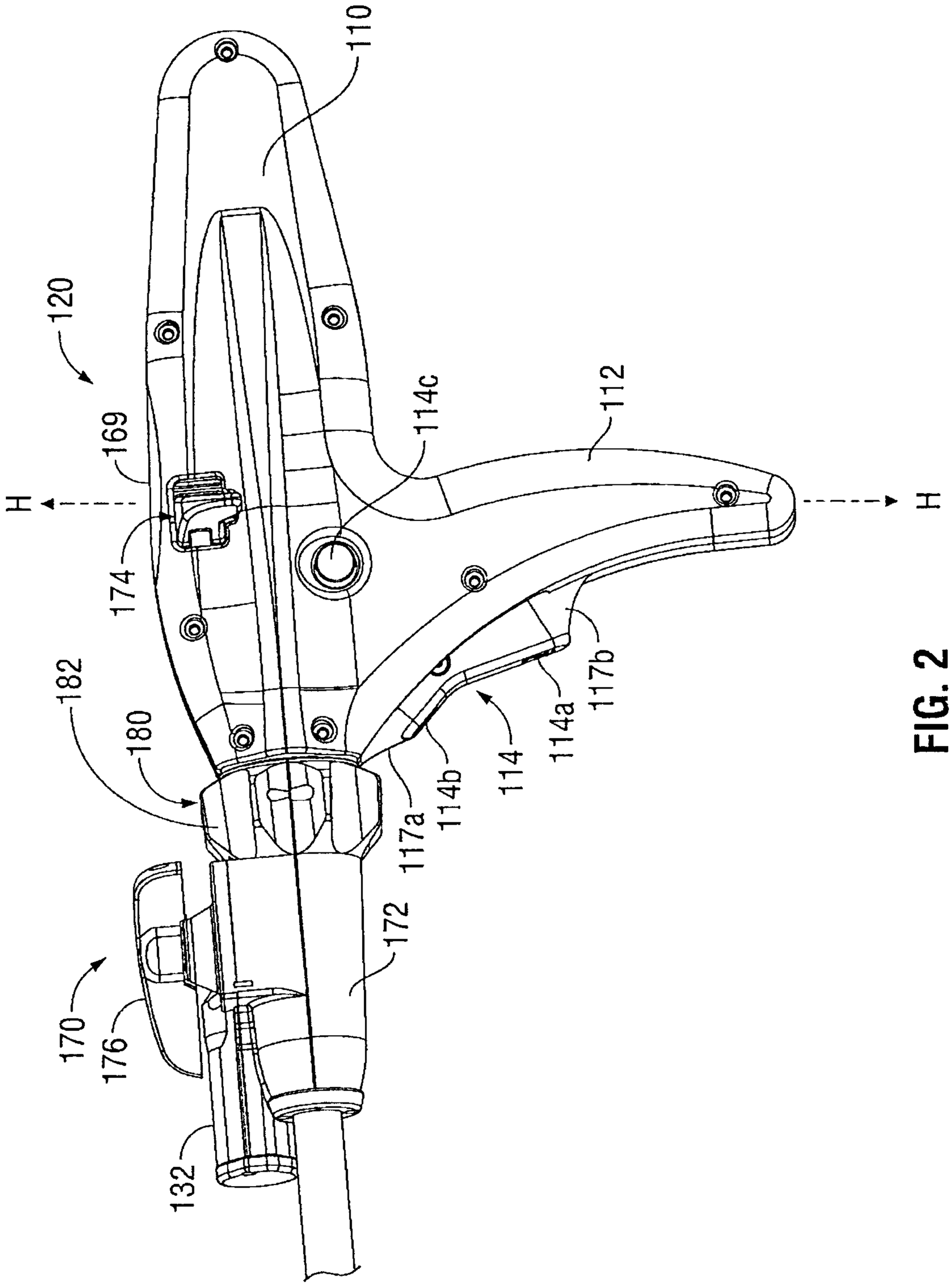
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FIG. 2

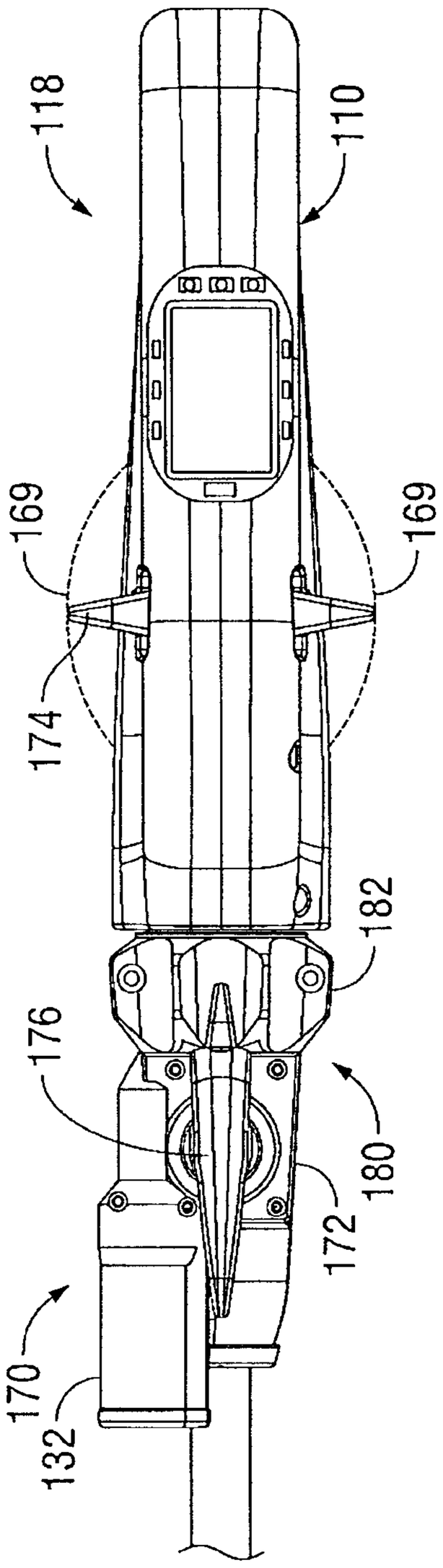
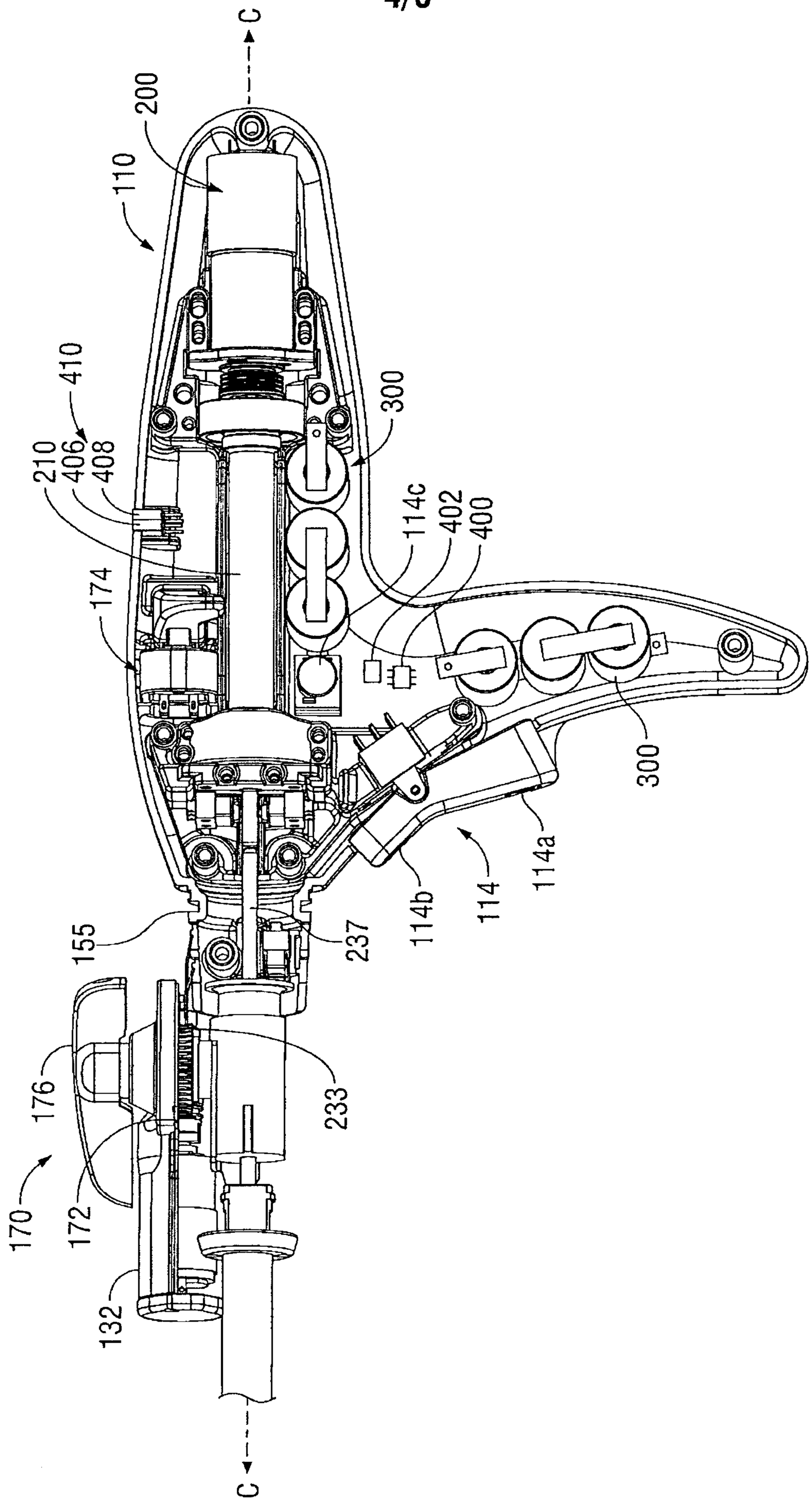


FIG. 3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110
410
210
406
408
174
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114
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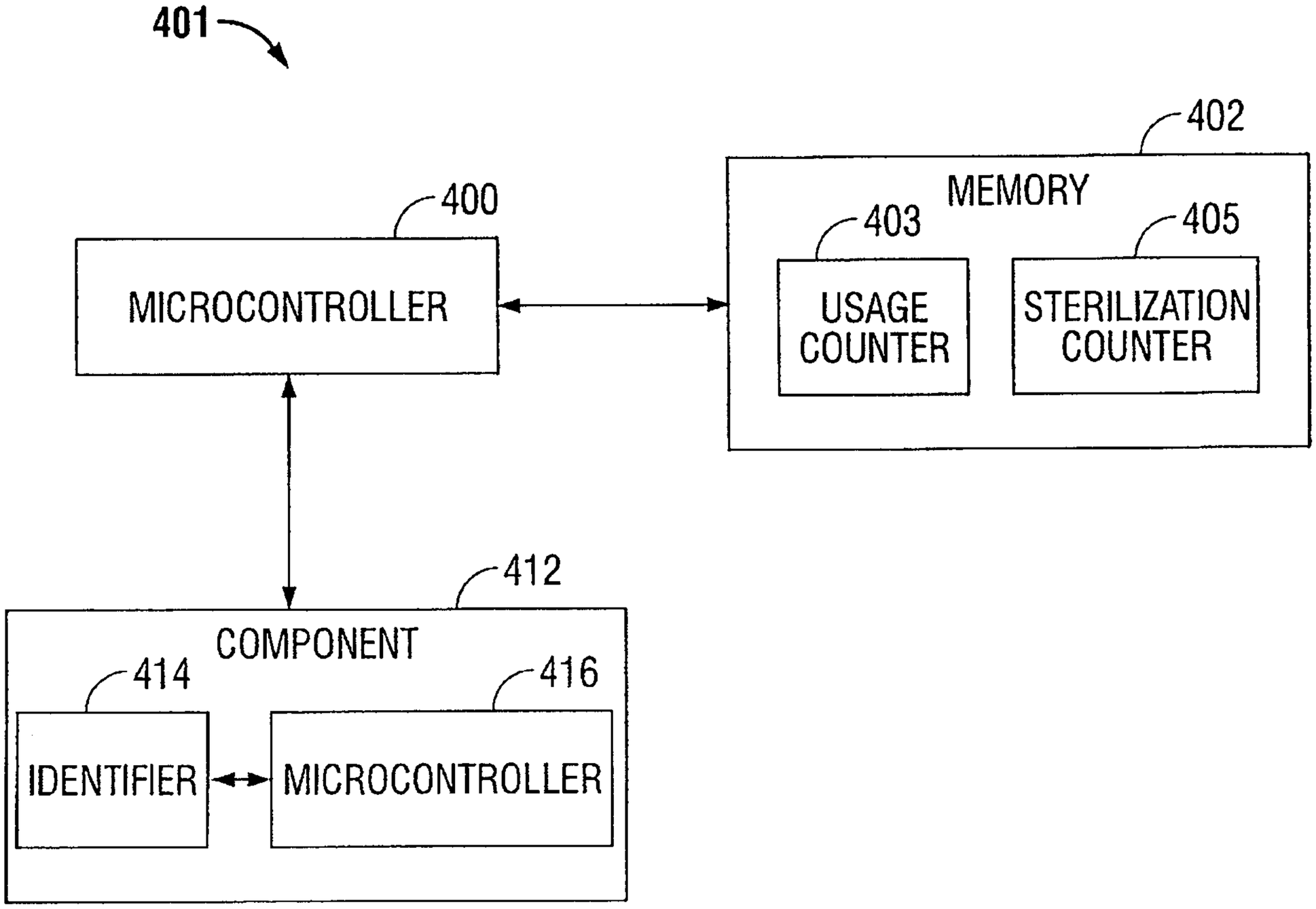
170
172
132
C

FIG. 4


401
402
MEMORY
400
MICROCONTROLLER
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USAGE COUNTER
405
STERILIZATION COUNTER
412
COMPONENT
414
IDENTIFIER
416
MICROCONTROLLER

FIG. 5

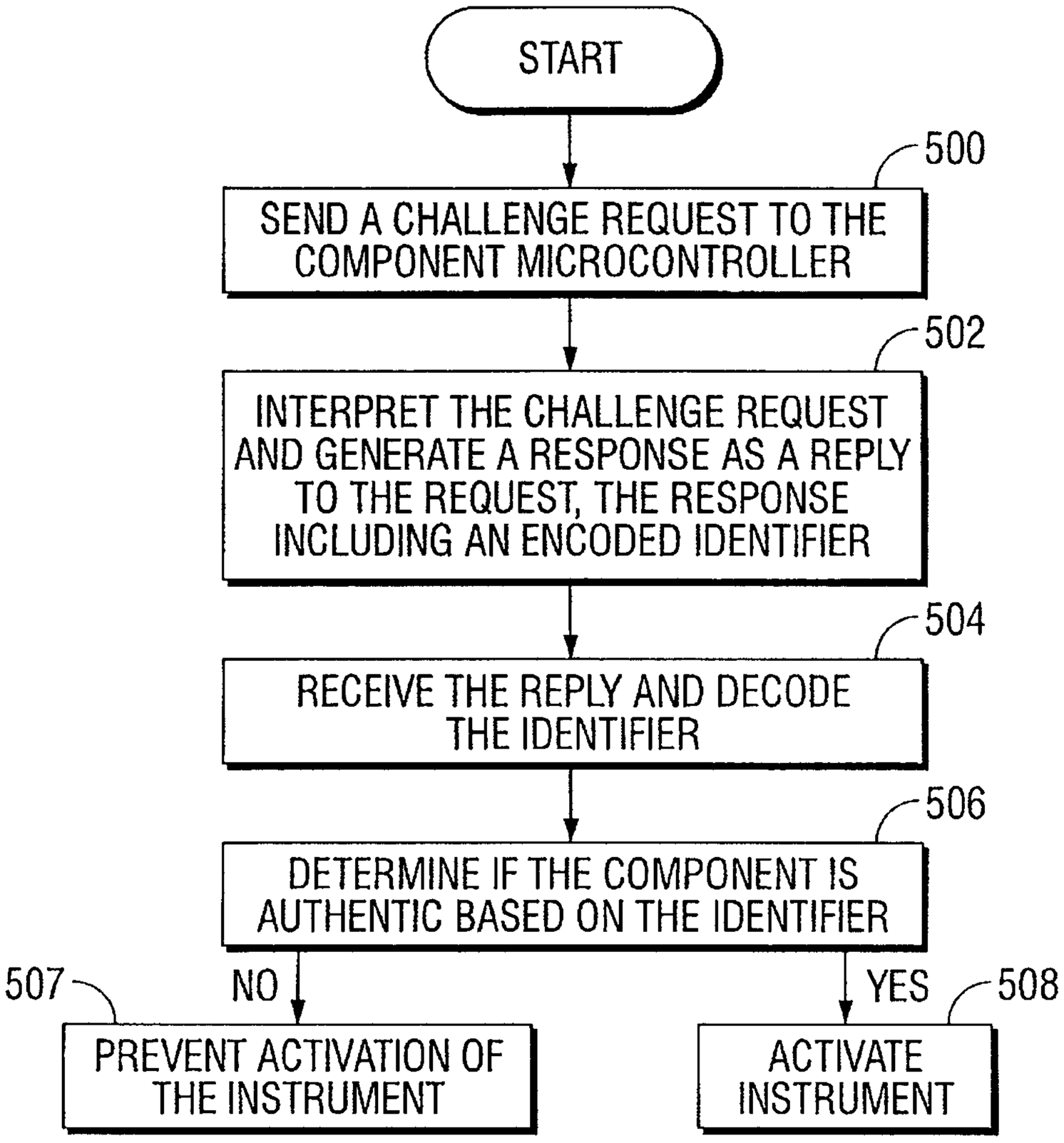
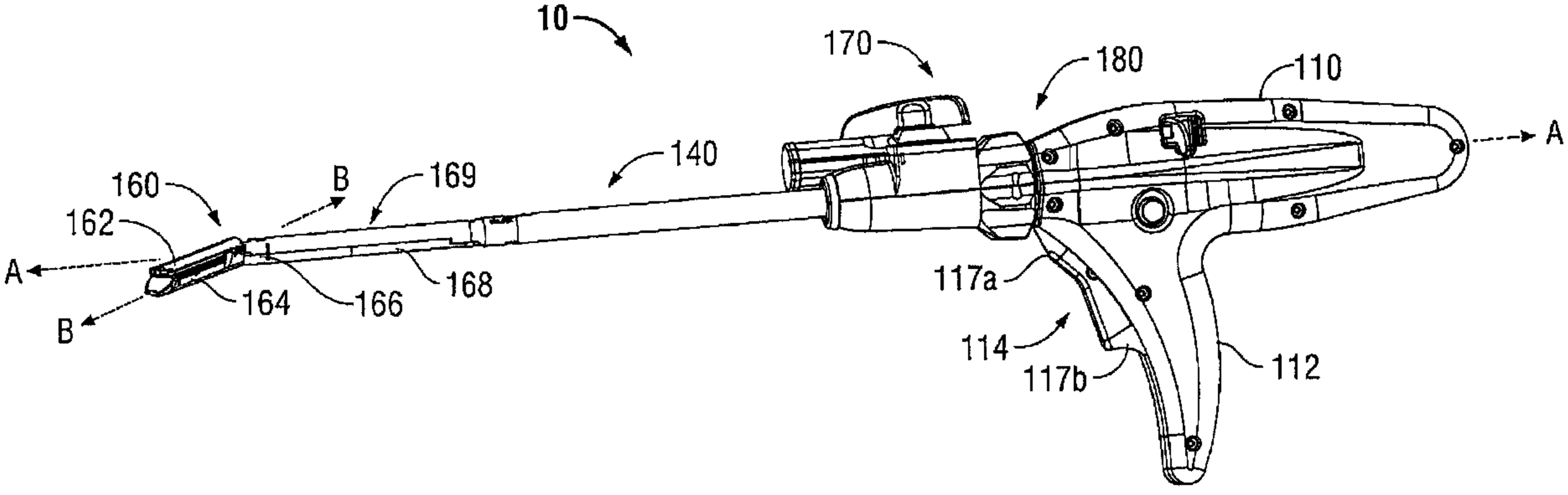

START
500
SEND A CHALLENGE REQUEST TO THE COMPONENT MICROCONTROLLER
502
INTERPRET THE CHALLENGE REQUEST AND GENERATE A RESPONSE AS A REPLY TO THE REQUEST, THE RESPONSE INCLUDING AN ENCODED IDENTIFIER
504
RECEIVE THE REPLY AND DECODE THE IDENTIFIER
506
DETERMINE IF THE COMPONENT IS AUTHENTIC BASED ON THE IDENTIFIER
NO
507
PREVENT ACTIVATION OF THE INSTRUMENT
YES
508
ACTIVATE INSTRUMENT

FIG. 6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